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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,460	07/18/2001	Lynn B. Lunsford	08191-014002	1198

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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
12/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	09/909,460	LUNSFORD ET AL.	
	Examiner	Art Unit	
	MARIA B. MARVICH	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,52,64-69 and 85-113* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 52, 64-69 and 85-113* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/29/09 has been entered.

Claims 1, 4, 52, 64-69 and 85-113 are pending in the application.

In the office action mailed 5/01/09, it was set forth that support for the limitation that a microparticle comprises in addition to a polymeric matrix and a nucleic acid, a lipid is found in the priority document PCT/US98/01499 filed 1/22/1998. PCT/US98/01499 teaches microparticles for delivery of nucleic acids wherein the particles comprise a polymeric matrix, nucleic acid and a stabilizing compound. This stabilizing compound can be a lipid such as CTAB and furthermore interacts with the nucleic acids of the particles. Therefore, PCT/US98/01499 supports the teachings of the instant specification and the instant claims. Therefore, the instant claims are afforded the priority date of PCT/US98/01499, 1/22/1998.

Claim Objections

Claims 66 and 96 are objected to because of the following informalities: Claim 66 and 96 should for accuracy be amended to recite, --wherein the synthetic polymeric matrix comprises a biodegradable copolymer--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 85, 88, 90-93, 95-100, 102 and 103 are rejected under 35 U.S.C. 102(b) as being anticipated by McElligott et al (WO 94/23738; see entire document). **This is a new rejection.**

McElligott et al teaches construction of microparticles of 1-250 microns wherein the microparticles comprise a polymeric matrix such as polycaprolactone or copolymers of lactic and glycolic acid encapsulating nucleic acid (see e.g. abstract, page 6, line 1-5, page 42, figure 2 and page 30, line 1-10) wherein the complex can further comprise lipid (see e.g. page 49, , claim 7). According to the specification such polymers have a solubility of less than about 1 mg/L. The nucleic acid is intended for expression and hence comprises expression control sequences, as well as sequences for immunization i.e. HIV (see page 12, line 13-23 and page 29, line 15-35). Example 1 teaches use of plasmid DNA that was no so treated to believe that it is less than 100% supercoiled. Targeting molecules are included (see e.g. page 7-27)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill

in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 52, 64-69 and 85-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over McElligott et al (Wo94/23738; see entire document) Hedley et al (US Patent 5,783,567; see entire document) in view of Balland et al (NATO ASI Series, 1996, Vol 290, pages 131-142; see entire document) in view of Knepp et al (US 6,264,990; see entire document). **This rejection is maintained for reasons of record in the office action mailed 12/1/08 and 6/2/09 and restated below.**

The instant claims are drawn to a micro particle less than 20 microns in diameter comprising a polymeric matrix, a lipid and a nucleic acid wherein the polymeric matrix has a solubility in water of at less then 1 mg/l and wherein at least 50% if the nucleic acids are supercoiled.

Hedley et al teach a microparticle as well as preparations of microparticles wherein the microparticles comprise a polymeric matrix and a nucleic acid expression vector. The polymeric matrix includes one or more synthetic polymers having a solubility of less then 1 mg/l that can be biodegradable. In certain cases, the polymeric matrix can be made of a single synthetic, biodegradable copolymer, e.g., poly-lactic-co-glycolic acid (PLGA). The ratio of lactic acid to glycolic acid in the copolymer can be within the range of about 1:2 to about 4:1 by weight, preferably within the range of about 1:1 to about 2:1 by weight, and most preferably about 65:35 by weight. In some cases, the polymeric matrix also includes a targeting molecule such as a ligand, receptor, or antibody, to increase the specificity of the microparticle for a given cell type or tissue type. The microparticles are at least 11 microns and the nucleic acid at least 80%

supercoiled (see e.g. col 1-2). The nucleic acid include an expression control sequence operatively linked to an expression predict encoding at least 7 amino acids having a sequence essentially identical to the sequence of either a fragment of a naturally-occurring mammalian protein or a fragment of a naturally-occurring protein from an agent which infects or otherwise harms a mammal; or a peptide having a length and sequence which permit it to bind to an MHC class I or II molecule (col 2, line 21-36).

Balland et al teach a microparticle less than 20 microns in diameter (see e.g. page 132, paragraph 4) comprising a polymeric matrix, a lipid and a nucleic acid (see e.g. page 132, paragraph 4- 5) and preparations of these microparticles (see e.g. page 133, paragraph 4).
As an initial point, KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness. See the recent Board decision Exparte Smith --USPD2d--., slip op. at 20, (BD. Pat. App. & Interfer. June 25, 2007). In this case each of Headley et al, McElligott et al and Balland et al teach design of microparticles that are less then 20 microns, as well as 11 microns. Each teaches that complexes of polymeric matrices and nucleic acids can be used to delivery the nucleic acids to cells. Headley et al and McElligott et al teach that the polymeric matrix is preferably one that has a solubility of less then 1mg/l as in the recited claims. Specifically, Headley et al and McElligott et al teach use of PLGA. Balland do not explicitly teach that the polymers have a solubility of less then 1mg/L however, these references do teach that it was known in the art to include lipids in the preparation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the lipid which functions as an ion pairing agent with the phosphate groups of the nucleic acids. Based upon the teachings of the cited references, the high skill of one of ordinary skill in

the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Response to Amendment

Applicants have filed the following statement

Statement Concerning Common Ownership
Application serial number 09/909,460 and U.S. Patent No. 5,783,567 were, at the time the currently claimed invention was made, owned by, or subject to an obligation of assignment to, Pangaea Pharmaceuticals, Inc. All of the inventors of U.S. Patent No. 5,783,567 assigned their rights in the patent to Pangaea Pharmaceuticals, Inc. in an assignment recorded in the U.S. Patent & Trademark Office on August 18, 1997, at Reel 8672, Frame 0675. All of the inventors of Application serial number 09/909,460 assigned their rights in the application to Pangaea Pharmaceuticals, Inc. in an assignment recorded in the U.S. Patent & Trademark Office on September 13, 1999, at Reel 010225, Frame 0212. Application serial number 09/909,460 and U.S. Patent No. 5,783,567 were both subsequently assigned to and are currently commonly owned by Eisai Inc.

In this case, the MPEP teaches

> For applications filed prior to November 29, 1999 and granted as patents prior to December 10, 2004, the subject matter that is disqualified as prior art under 35 U.S.C. 103(c) is strictly limited to subject matter that A) qualifies as prior art only under 35 U.S.C. 102(f) or 35 U.S.C. 102(g), and B) was commonly owned with the claimed invention at the time the invention was made.

It is applicants contention that the subject matter was invented with PCT/US98/01999 1/22/1998 and hence the statement above does not indicate that the inventions were commonly owned at the time the invention was made as the assignment of 09/909460 was made 9/13/1999. To this end, the MPEP teaches,

> If the subject matter that qualifies as prior art only under 35 U.S.C. 102(f) or 35 U.S.C. 102(g) was not commonly owned at the time of the invention, the subject matter is not disqualified as prior art under 35 U.S.C. 103(c). See OddzOn Products, Inc. v. Just Toys, Inc., 122 F.3d 1396, 1403-04, 43 USPQ2d 1641, 1646 (Fed. Cir. 1997) ("We therefore

hold that subject matter derived from another not only is itself unpatentable to the party who derived it under § 102(f), but, when combined with other prior art, may make a resulting obvious invention unpatentable to that party under a combination of §§ 102(f) and 103.") Therefore, in these applications, information learned from or transmitted to persons outside the organization is not disqualified as prior art. Inventors of subject matter not commonly owned at the time of the invention, but currently commonly owned, may file as joint inventors in a single application. However, the claims in such an application are not protected from a 35 U.S.C. 103 rejection based on prior art under 35 U.S.C. 102(f) or 102(g). Applicants in such cases have an obligation pursuant to 37 CFR 1.56 to point out the inventor and invention dates of each claim and the lack of common ownership at the time the later invention was made to enable the examiner to consider the applicability of a 35 U.S.C. 103 rejection based on prior art under 35 U.S.C. 102(f) or 102(g). The examiner will assume, unless there is evidence to the contrary that applicants are complying with their duty of disclosure. Foreign applicants will sometimes combine the subject matter of two or more related applications with different inventors into a single U.S. application naming joint inventors. The examiner will make the assumption, absent contrary evidence, that the applicants are complying with their duty of disclosure if no information is provided relative to invention dates and common ownership at the time the later invention was made. Such a claim for 35 U.S.C. 119(a)-(d) priority based upon the foreign filed applications is appropriate and 35 U.S.C. 119(a)-(d) priority can be accorded based upon each of the foreign filed applications.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Primary Examiner
Art Unit 1633

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